Patient-Centered Biosimilars Communications Policies

Recommendations For Health Plans

Our organizations believe patient confidence in biosimilars is critical to avoid a negative patient experience or adverse impacts like the "nocebo effect" in which a patient has a negative health outcome out of a belief that the drug they took was lesser. It is therefore in every stakeholder's best interest to prioritize proactive education and communication processes that meaningfully address patient questions and concerns, and we believe every health care stakeholder has a distinct responsibility in communicating with patients. Health plans are in a powerful position to influence patient confidence.

Below please find specific recommendations for patient communications, based on patient data from our organizations.

Use FDA recommendations and language as a model in external and patient-facing materials. Specific recommendations include:

1. Avoid using the term "reference product" and instead use "brand" or "original." In a 2022 Arthritis Foundation (AF) survey, 65% of patients had not heard the term "reference product."
2. Clearly define the term "biosimilars" in patient-friendly language, such as "a biosimilar is a type of biologic used to treat certain forms of arthritis, Crohn's disease, ulcerative colitis, psoriasis and psoriatic arthritis. They are FDA approved as having no clinically-meaningful difference from the original brand drug." 49% of AF survey respondents had never heard the term "biosimilar," and only 21% had a good understanding of biosimilars.
3. Link to the FDA's patient education resources in each patient communication.

Ensure patient communications about any switch to a biosimilar occur well in advance of a switch.

1. Notify providers in advance of a formulary change and encourage in-network providers to have conversations with their patients about switches.
2. Notify patients at least 30 days in advance. 85% of those surveyed would want to know if they were receiving a biosimilar in place of their biologic, and 69% would want to know well in advance. Communications should include:
    - Specifics about what the switch is and where they can find more information about the product
    - Specific information about the product such as if it is citrate-free and if it has a different injection device, in addition to how to learn to use the new medication
    - Any delivery method changes such as pharmacy and mail-order requirement
    - Any cost-sharing changes, and in particular a notification of any cost savings to them
    - Where to go with any questions and concerns; ideally the patient is offered counseling services by the health plan to talk through any changes

- How to appeal if the medication does not work as well or if the patient's provider believes a switch should not occur due to specific patient circumstance. NOTE: the top question patients had in our survey was what to do if the medication doesn't work.

3. Communicate with patients through multiple methods, such as patient portals, email, text, and written mail. Our surveys show email as the top preferred source of information, followed by patient portals and written mail, though focus group respondents overwhelmingly believed stakeholders should utilize multiple methods of communication.

Highlight safety and clinical efficacy data in communications about biosimilars.

1. Safety risks, treatment efficacy and side effects are types of information of most interest to patients; patient communications should provide information and links for specific data on these topics.
2. Communications should include a combination of information about clinical safety and effectiveness and stories from other patients who have switched to biosimilars.
3. 67% of AF survey respondents would be open to using a biosimilar if they had more information; however, only 23% would be comfortable using one with what they know right now.

Ensure that any communications include links to educational resources or toll-free helplines provided by national patient organizations.

1. Patient organizations can provide information to patients in addition to connecting them with trained experts and other patients. We encourage health plans to include links such as:
    a. Arthritis Foundation Helpline and biosimilars landing page
    b. National Psoriasis Foundation Patient Navigation Center and biosimilars landing page
    c. Crohn's & Colitis Foundation IBD Help Center and biosimilars landing page.

Tailor messaging for different scenarios, e.g., patients who have never used a reference biologic

1. AF survey data showed biologic-naïve patients were more concerned with side effects (91%), how often the medication would be taken (69%), and how the medication is taken (79%), in addition to overall comparisons to other types of treatments (64%).
2. Biologic experienced patients were significantly more concerned with specific details around making the switch to biosimilars than biologic naïve patients. Emphasizing safety and efficacy data is particularly important for those switching directly from the reference product (86%). Real world data about switches is significantly more important to biologic experienced patients than those who are biologic naïve (53% vs 45%).

Please contact Anna Hyde at ahyde@arthritis.org, Jason Harris at jharris@psoriasis.org, or Cassie Ray at cray@crohnscolitisfoundation.org with any questions or if we can be of further assistance.